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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/03/97	10/29/97	ILLUMIN	

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WASHINGTON DC 20036

EXAMINER

INVENTOR

ART UNIT	PAPER NUMBER
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12

DATE MAILED: 02/12/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/29/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-1LP is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-1LP is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

DETAILED ACTION

1. Applicant's amendment filed 10/29/96 has been received. Claims 1-16 are pending.
2. The text of those U.S. Codes not found in this office action may be found in the previous office action, paper no. 8.

Specification

3. The disclosure is objected to because of the following informalities: page 3, 4th line from the bottom of the page, "specifically" should be --specifically--. Page 4, line 17, "alifatic" should be --aliphatic--, and page 5, 5th line from the bottom of the page, the abbreviation "SPDP" should be completely spelled out.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claim 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite ~~because~~ with respect to the recitation of "binds a protein...to a surface in the biosensor". It is unclear if this is the same surface where the carbohydrate derivative is bound or is it a different surface? In other words, does the protein, virus or cell bind a surface of the biosensor or do they bind the carbohydrate derivative which is on the biosensor?

Claims 2 and 8 are vague and indefinite with respect to the recitation of "the biosensor signal transducer part" because it lacks antecedent support in claim 1 from which they depend.

Claims 6 and 7 are vague and indefinite with respect to the recitation of "the aglycon part" because it lacks antecedent support in claim 1 from which they depend.

Claims 8, 9 and 13 are vague and indefinite with respect to the recitation of "said surface" because it is unclear if this is the surface where the carbohydrate derivative is bound or is it another surface on the biosensor? See discussion of claim 1 above.

Claim 9 is vague and indefinite with respect to the recitation of "at the binding" because it lacks antecedent support. Examiner suggests reciting --upon binding-- to obviate the rejection.

Claim 14 is objected to because of the recitation of non-conventional claim language, i.e. "characterised". It is suggested that --wherein-- be used instead.

Claim 14 is also vague and indefinite with respect to the recitation of "can be used" because it is unclear if the organic group is or is not used for chemical binding. Examiner suggests using --is used-- to obviate the rejection.

Claim 15 is vague and indefinite with respect to the recitation of "modified" because it is unclear how the surface is modified.

Claim 16 provides for the use of a biosensor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

5. Claims 1, 2, 9, 10, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Attridge et al (WO 90/01166) for reasons of record in the prior office action, paper no. 8.

6. Claims 1, 2, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Karube (EP 0 215 669) for reasons of record in the prior office action, paper no. 8.

Claim Rejections - 35 USC § 103

7. Claims 3-8 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Attridge et al in view of Nilsson et al (US Patent No. 4,918,009) for reasons of record in the prior office action, paper no. 8.
8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Attridge et al for reasons of record in the prior office action, paper no. 8.

Response to Arguments

9. Applicant's arguments filed 10/29/96 have been fully considered but they are not persuasive. Applicant argues that Attridge et al differ from the instant invention because Attridge et al teaches carbohydrate as one of the binding partners which may be used and Applicant asserts the instant claims, 1 and 2, call for a cellulose derivative. This argument is not persuasive because claims 1 and 2 only recite a carbohydrate derivative. Neither one of these claims is limited to a cellulose derivative. Further, this argument is not persuasive because the feature upon which Applicant relies, *i.e.* cellulose, is not recited in the rejected claims.

Applicant argues that Karube differs from the instant invention because Karube fails to teach the use of sugars or carbohydrates for use in the biosensor. This argument is not persuasive because Karube teaches, on page 6, lines 15-24, the use of receptors such as enzymes, sugars (carbohydrates), lipids, co-enzymes, amino acids and proteins, such as lectins, antibodies etc. immobilized on the surface of the piezoelectric crystal of a biosensor. Therefore, Karube is seen to anticipate the instant claims.

Applicant argues that the 103 rejection over Attridge et al in view of Nilsson is unsupported because Nilsson teaches methods for the synthesis of carbohydrates and carbohydrate glycosides and the examples show carbohydrates and not carbohydrate derivatives. Further, Nilsson does not teach the use of carbohydrate derivatives for coupling to biosensor surfaces. This argument is not persuasive because Nilsson specifically teaches the synthesis of carbohydrates as well as a variety of carbohydrate derivatives at columns 3-8. Nilsson also teach

that these carbohydrate derivatives may be immobilized on solid carriers for use in diagnostic assays (column 7, lines 26-29, column 15, lines 10-13 and column 20, lines 34-39).

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references.

Applicant also argues that it is not obvious to combine because no motivation exists for modifying the Attridge et al reference with the carbohydrate derivatives of Nilsson. This argument is not persuasive because the solid phase taught by Nilsson is seen to be functionally equivalent with the biosensor surface of Attridge et al (*i.e.* they are both solid carriers), therefore, one of ordinary skill in the art would have been motivated to use the carbohydrate derivatives of Nilsson in the biosensor of Attridge et al because Attridge et al teach that their biosensor may be used to immobilize a variety of substances including carbohydrates.

Applicant argues that the instant invention teaches the use of thiol containing compounds for binding to the carbohydrate derivative by way of the sulphur atom directly on the gold surface, and that this method binding has not been previously suggested. This argument is not persuasive because the feature upon which applicant relies (*i.e.* having the sulphur atom directly on the gold surface) is not recited in the rejected claim.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday through Friday, from 7:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

BTN
February 3, 1997


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800